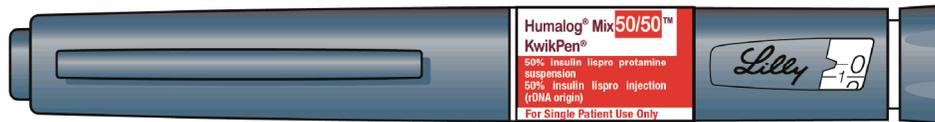


Instructions for Use

HUMALOG[®] Mix50/50[™] KwikPen[®]

50% insulin lispro protamine suspension and
50% insulin lispro injection (rDNA origin)

100 units/mL, 3 mL pen



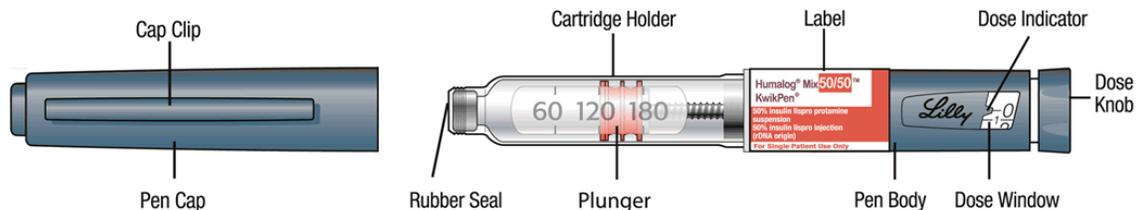
Read the Instructions for Use before you start taking HUMALOG Mix50/50 and each time you get another KwikPen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Do not share your HUMALOG Mix50/50 KwikPen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

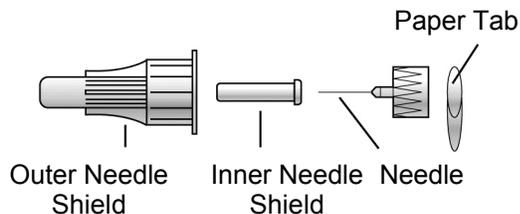
HUMALOG[®] Mix50/50[™] KwikPen[®] (“Pen”) is a disposable prefilled pen containing 300 units of HUMALOG Mix50/50. You can give yourself more than 1 dose from the Pen. Each turn (click) of the Dose Knob dials 1 unit of insulin. You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than 1 injection.** The Plunger only moves a little with each injection, and you may not notice that it moves. The Plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.

KwikPen Parts



Pen Needle Parts (Needles Not Included)



Dose Knob



How to recognize your HUMALOG Mix50/50 KwikPen

- Pen color: Dark blue
- Dose Knob: Dark blue
- Labels: White label with red stripe

Supplies you will need to give your injection

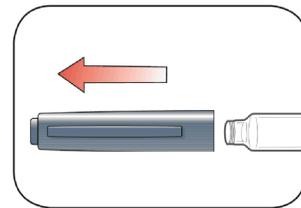
- HUMALOG Mix50/50 KwikPen
- KwikPen compatible Needle (Becton, Dickinson and Company Pen Needles recommended)
- Alcohol swab
- Gauze

Preparing your Pen

- Wash your hands with soap and water.
- Check your Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label or for more than 10 days after you first start using the Pen.
- **Always use a new needle for each injection to help prevent infections and blocked needles. Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.**

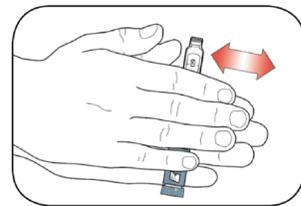
Step 1:

- Pull the Pen Cap straight off.
 - **Do not** remove the Pen Label.
- Wipe the Rubber Seal with an alcohol swab.
 - **Do not** attach the Needle before mixing.



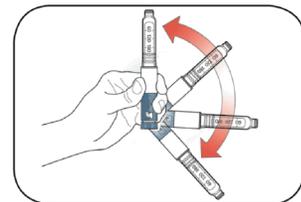
Step 2:

- Gently roll the Pen between your hands 10 times.



Step 3:

- Move the Pen up and down (invert) 10 times.
Mixing by rolling and inverting the Pen is important to make sure you get the right dose.

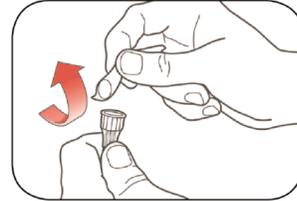


Step 4:

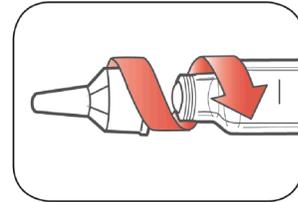
- **Check the liquid in the Pen.**
HUMALOG Mix50/50 should look white and cloudy after mixing. **Do not** use if it looks clear or has any lumps or particles in it.
-

Step 5:

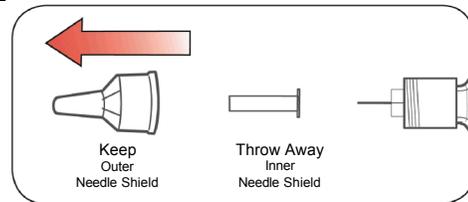
- **Select a new Needle.**
- Pull off the Paper Tab from the Outer Needle Shield.

**Step 6:**

- Push the capped Needle straight onto the Pen and twist the Needle on until it is tight.

**Step 7:**

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



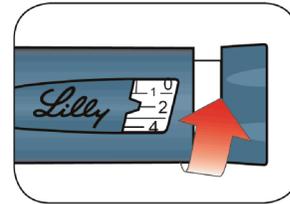
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

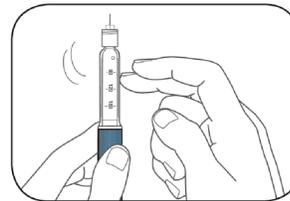
Step 8:

- To prime your Pen, turn the Dose Knob to select 2 units.



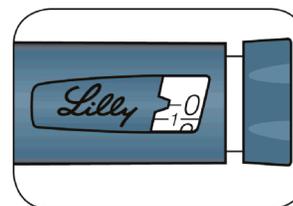
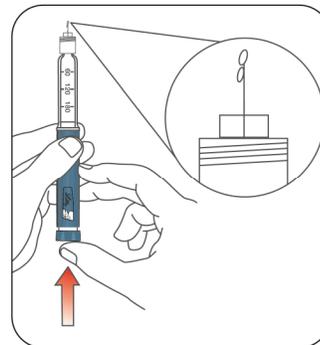
Step 9:

- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top.



Step 10:

- Continue holding your Pen with Needle pointing up. Push the Dose Knob in until it stops, and "0" is seen in the Dose Window. Hold the Dose Knob in and **count to 5 slowly**.
- You should see insulin at the tip of the Needle.
 - If you **do not** see insulin, repeat priming steps 8 to 10, no more than 4 times.
 - If you **still do not** see insulin, change the Needle and repeat priming steps 8 to 10.



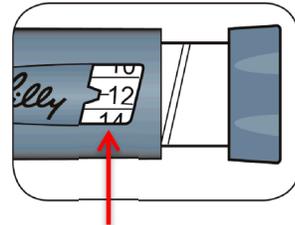
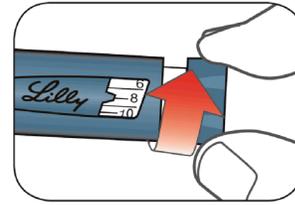
Small air bubbles are normal and will not affect your dose.

Selecting your dose

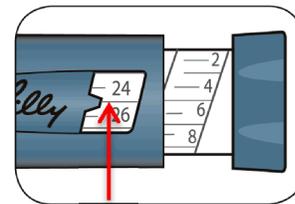
- You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give more than one injection.
 - If you need help with dividing up your dose the right way, ask your healthcare provider.
 - Use a new Needle for each injection and repeat the priming step.

Step 11:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Pen dials 1 unit at a time.
 - The Dose Knob clicks as you turn it.
 - **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
 - The **even** numbers (for example, 12) are printed on the dial.
 - The **odd** numbers, (for example, 25) after the number 1, are shown as full lines.
- **Always check the number in the Dose Window to make sure you have dialed the correct dose.**



(Example: 12 units shown in the Dose Window)



(Example: 25 units shown in the Dose Window)

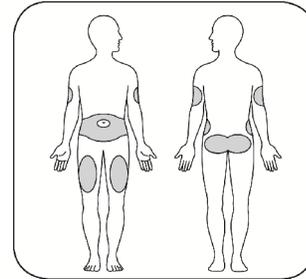
- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose, **or**
 - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you can not inject.

Giving your injection

- Inject your insulin as your healthcare provider has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

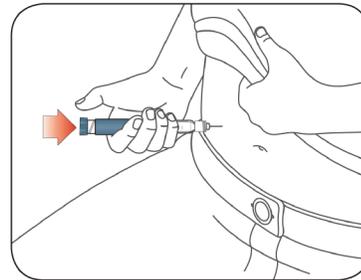
Step 12:

- Choose your injection site.
HUMALOG Mix50/50 is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe your skin with an alcohol swab, and let your skin dry before you inject your dose.



Step 13:

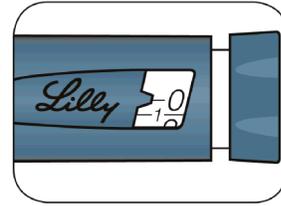
- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob in and **slowly count to 5** before removing the Needle.



Do not try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.

Step 14:

- Pull the Needle out of your skin.
A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window.
 - If you see “0” in the Dose Window, you have received the full amount you dialed.
 - If you do not see “0” in the Dose Window, do not redial. Insert the Needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat the injection.** Monitor your blood glucose as instructed by your healthcare provider.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.



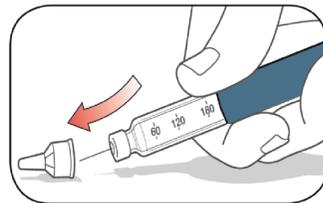
The Plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.

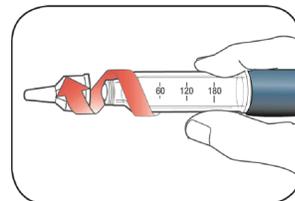
After your injection

Step 15:

- Carefully replace the Outer Needle Shield.

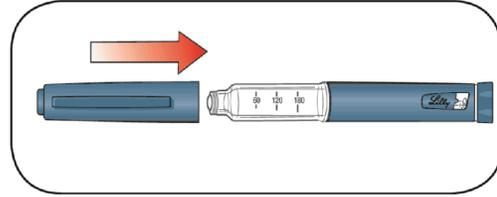
**Step 16:**

- Unscrew the capped Needle and throw it away (see **Disposing of Pens and Needles** section).
- **Do not** store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 17:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Disposing of Pens and Needles

- Put your used needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- The used Pen may be discarded in your household trash after you have removed the needle.

Storing your Pen

Unused Pens

- Store unused Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- **Do not** freeze your insulin. **Do not** use if it has been frozen.
- Unused Pens may be used until the expiration date printed on the Label, if the Pen has been kept in the refrigerator.

In-use Pen

- Store the Pen you are currently using at room temperature [up to 86°F (30°C)]. Keep away from heat and light.
- Throw away the HUMALOG Mix50/50 Pen you are using after 10 days, even if it still has insulin left in it.

General information about the safe and effective use of your Pen

- **Keep your Pen and needles out of the reach of children.**
- **Do not** use your Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you can not remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the Dose Knob is hard to push:
 - Pushing the Dose Knob more slowly will make it easier to inject.
 - Your Needle may be blocked. Put on a new Needle and prime the Pen.
 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

If you have any questions or problems with your HUMALOG Mix50/50 KwikPen, contact Lilly at 1-800-LillyRx (1-800-545-5979) or call your healthcare provider for help. For more information on HUMALOG Mix50/50 KwikPen and insulin, go to www.humalog.com.



Scan this code to launch

www.humalog.com

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Revised: January 6, 2017

**Marketed by: Lilly USA, LLC
Indianapolis, IN 46285, USA**

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HUMALOG Mix50/50 KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1:2014.

LOG5050KP-0002-IFU-20170106